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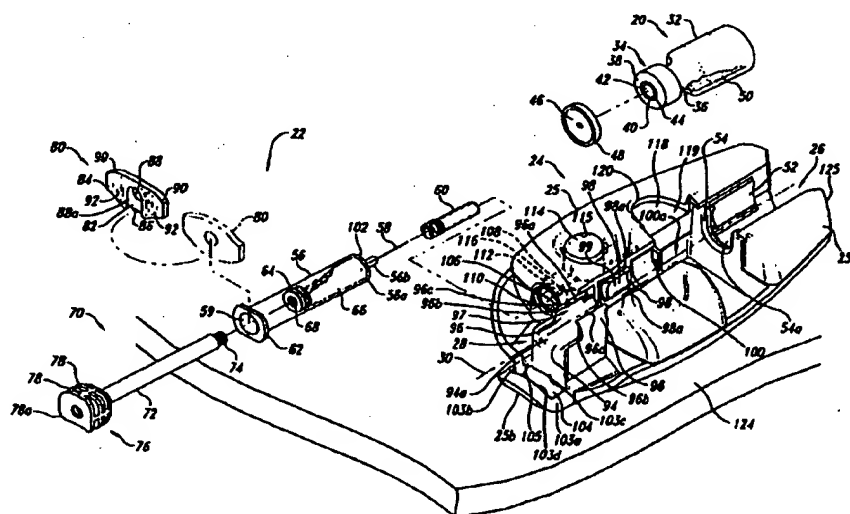
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(21) International Application Number: PCT/US99/23594 (22) International Filing Date: 8 October 1999 (08.10.99) (30) Priority Data: 60/106,435 30 October 1998 (30.10.98) US (71) Applicant (for all designated States except US): IMMUNEX CORPORATION [US/US]; 51 University Street, Seattle, WA 98101 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): COLEMAN, W., Carl [US/US]; 3715 South Andover Street, Seattle, WA 98118 (US). BODE, Robert, L. [US/US]; 10658 Manitou Park Boulevard, Bainbridge Island, WA 98110 (US). LUCIANO, Robert, C. [US/US]; Suite N, 724 N. Western Street, Parkridge, IL 60068 (US). (74) Agents: WECHKIN, John, M. et al.; Perkins Coie LLP, Suite 4800, 1201 Third Avenue, Seattle, WA 98101-3099 (US).	(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, S OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, MR, NE, SN, TD, TG). Published <i>With international search report.</i> (88) Date of publication of the international search report: 24 August 2000 (24.08)	

(54) Title: METHOD AND APPARATUS FOR OPERATING A SYRINGE AND VIAL FOR INJECTIONS



(57) Abstract

A device for aligning a vial and a syringe used for medical injections. The device includes a vial alignment portion and a syringe alignment portion, both aligned on an alignment axis extending between the two portions. The alignment portions can restrict motion both the vial and the syringe transverse to the alignment axis so as to maintain a needle of the syringe aligned with an access port of the vial. The device can also include provisions for removing a protective cap from the vial and for removing a protective cover from the syringe needle. The syringe and the vial can be packaged in a container which can also be used to align the syringe with the vial.

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CLAIMS

1. A reusable device for aligning a syringe with a vial, the device comprising a body having a vial alignment portion and a syringe alignment portion aligned on an alignment axis extending between the vial alignment portion and the syringe alignment portion, the vial alignment portion having at least one vial engagement surface shaped to releasably and reusably engage the vial, the syringe alignment portion having at least one syringe engagement surface shaped to releasably and reusably engage the syringe, the syringe engagement surface including a first portion adjacent the syringe and a second portion adjacent the syringe and extending around a portion of the syringe sufficient to at least restrict motion of the syringe in any direction transverse to the alignment axis.
2. The device of claim 1 wherein the vial alignment portion includes a first vial arm and a second vial arm generally opposite the first vial arm, the first and second vial arms having concave surfaces adjacent the vial.
3. The device of claim 2 wherein at least one of the first and second vial arms is biased toward the other to clamp the vial between the vial arms.
4. The device of claim 1 wherein the syringe alignment portion includes a first syringe arm and a second syringe arm spaced apart from the first syringe arm, the first and second syringe arms having concave surfaces adjacent the syringe.
5. The device of claim 4 wherein at least one of the first and second syringe arms is biased toward the other of the first and second syringe arms to clamp the syringe between the syringe arms and center the syringe generally on the alignment axis.
6. The device of claim 1 wherein the syringe alignment portion includes a first syringe arm and a second syringe arm spaced apart from the first syringe arm, the first and second syringe arms having concave surfaces proximate the syringe, the concave surfaces

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being spaced apart by a distance greater than a diameter of the syringe so the syringe fits loosely therebetween, the concave surfaces being spaced closely enough to at least restrict motion of the syringe transverse to the alignment axis.

7. The device of claim 1 wherein the first portion of the syringe engagement surface is concave, faces upwardly and extends axially beyond the second portion of the engagement surface to receive the syringe when the syringe is moved generally downwardly toward the first portion of the syringe engagement surface.

8. The device of claim 1 wherein the syringe includes a barrel, a needle projecting from the barrel and a cover covering the needle and removably coupled to the barrel, further wherein the body has a cover removing portion that includes first and second cover engaging surfaces spaced apart to clamp the cover therebetween.

9. The device of claim 8 wherein the cover engaging surfaces are spaced apart by a distance that is greater than a diameter of the cover to allow the cover to be positioned between the cover engaging surfaces, and at least one of the cover engaging surfaces is movable relative to the other.

10. The device of claim 8, further comprising the syringe, wherein the syringe is sterile.

11. The device of claim 1 wherein the vial includes a removable cap having a generally flat upper surface and a cap lip extending around the upper surface and projecting away from the vial, further wherein the body includes a cap removing portion having a generally flat receiving surface to receive the upper surface of the cap, the cap removing portion further having an overhanging lip engaging surface opposite the receiving surface to engage the lip when the cap is received on the receiving surface.

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12. A reusable device for aligning a syringe with a vial, the device comprising a body having a vial alignment portion and a syringe alignment portion aligned on an alignment axis extending between the vial alignment portion and the syringe alignment portion, the vial alignment portion having at least one vial engagement member to releasably and reusably engage the vial, the syringe alignment portion having at least one syringe engagement member to releasably and reusably engage the syringe, the syringe engagement member being positioned to extend around and engage the syringe when the syringe is positioned therebetween to restrict motion of the syringe in any direction transverse to the alignment axis.

13. The device of claim 12, further comprising another syringe engagement member axially spaced apart from the at least one syringe engagement member to releasably and reusably engage the syringe.

14. The device of claim 12 wherein the vial engagement member includes a first vial arm and a second vial arm generally opposite the first vial arm on opposing sides of the alignment axis, the first and second vial arms being spaced apart and having concave surfaces sized and shaped to receive the vial therebetween and to engage and grasp a convex exterior surface of the vial when the vial is between the first and second vial arms, at least one of the first and second vial arms being biased toward the other to releasably clamp the vial between the first and second vial arms when received therebetween and center the vial generally on the alignment axis.

15. The device of claim 12 wherein the syringe engagement member includes a first syringe arm and a second syringe arm generally opposite the first syringe arm on opposing sides of the alignment axis, the first and second syringe arms being spaced apart and having concave surfaces sized and shaped to receive the syringe therebetween.

16. The device of claim 12 wherein at least one of the first and second syringe arms is biased toward the other to releasably clamp the syringe between the first and

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second syringe arms when the syringe is received therebetween and center the syringe generally on the alignment axis.

17. The device of claim 16 for use with a syringe having a barrel with a needle exterior therefrom, wherein the first and second syringe arms each have a free end positioned spaced apart from the other to provide a gap therebetween of sufficiently large size for lateral passage of the syringe needle therethrough but of sufficiently small size to prevent lateral passage of the syringe barrel therethrough.

18. The device of claim 12 wherein the syringe engagement member includes a first syringe arm and a second syringe arm, the first syringe arm and the second syringe arm being generally on opposite sides of the alignment axis, the first and second syringe arms being spaced apart and having concave surfaces sized and shaped to loosely receive the syringe therebetween and to at least restrict motion of the syringe transverse to the alignment axis when the syringe is between the first and second syringe arms.

19. The device of claim 12 for use with a syringe barrel having an end portion from which a needle extends, wherein the syringe engagement portion further includes a guide surface to engage the barrel end portion, the syringe engagement member being between the guide surface and the vial engagement member, the guide surface extending in a direction along the alignment axis away from the vial engagement member.

20. The device of claim 12 for use with a syringe having a barrel, a needle projecting from the barrel and a cover covering the needle and removably coupled to the barrel, wherein the body has a needle cover removing portion that includes first and second needle cover engaging surfaces spaced apart to receive and clamp the needle cover therebetween.

21. The device of claim 12 for use with a vial having a removable cap with a generally flat upper surface and a cap lip extending around the upper surface and projecting

away from the vial, wherein the body includes a cap removing portion having a generally flat receiving surface to receive the upper surface of the cap, the cap removing portion further having an overhanging lip engaging surface opposite the receiving surface and spaced apart sufficiently to receive therebetween and engage the cap lip when the upper surface of the cap is received on the receiving surface.

22. A reusable device for aligning a syringe with a vial, the device comprising a body having a vial alignment portion and a syringe alignment portion aligned on an alignment axis extending between the vial alignment portion and the syringe alignment portion, the vial alignment portion having at least one vial engagement member to releasably and reusably engage the vial, the syringe alignment portion having first and second syringe engagement members to releasably and reusably engage the syringe, the first and second syringe engagement members being spaced apart along the alignment axis, the first syringe engagement member positioned to engage and center the syringe generally on the alignment axis when the syringe is in the syringe alignment portion, the second syringe engagement member including first and second portions positioned to extend around and engage the syringe when therebetween to restrict motion of the syringe in any direction transverse to the alignment axis.

23. The device of claim 22 wherein the vial engagement member includes a first vial arm and a second vial arm generally opposite the first vial arm on opposing sides of the alignment axis, the first and second vial arms being spaced apart and having concave surfaces sized and shaped to receive the vial, therebetween and to engage and grasp a convex exterior surface of the vial when the vial is between the first and second vial arms, at least one of the first and second vial arms being biased toward the other to releasably clamp the vial between the first and second vial arms when received therebetween and center the vial generally on the alignment axis.

24. The device of claim 22 for use with a vial having at least one inclined surface inclined relative to the alignment axis wherein the vial alignment portion includes a

vial stop surface facing the inclined surface of the vial and positioned to prevent motion of the vial beyond a selected position along the alignment axis.

25. The device of claim 22 wherein the second syringe engagement member first portion includes a first syringe arm and the second syringe engagement member second portion includes a second syringe arm generally opposite the first syringe arm on opposing sides of the alignment axis, the first and second syringe arms being spaced apart and having concave surfaces sized and shaped to receive the syringe therebetween and to engage and grasp a convex exterior surface of the syringe when the syringe is between the first and second syringe arms, at least one of the first and second syringe arms being biased toward the other to releasably clamp the syringe between the first and second syringe arms when received therebetween and center the syringe generally on the alignment axis.

26. The device of claim 22 wherein the first syringe engagement member includes first and second syringe arms generally on opposite sides of the alignment axis, the first and second syringe arms being spaced apart and having concave surface sized and shaped to loosely receive the syringe therebetween and to at least restrict motion of the syringe transverse to the alignment axis when the syringe is between the first and second syringe arms.

27. The device of claim 26 for use with a syringe having a barrel with a needle exterior therefrom, wherein the first and second syringe arms of the first syringe engagement member each have a free end positioned spaced apart from the other to provide a gap therebetween of sufficiently large size for lateral passage of the syringe needle therethrough but of sufficiently small size to prevent lateral passage of the syringe barrel therethrough.

28. The device of claim 26 wherein the second syringe engagement member first portion includes a first syringe arm and the second syringe engagement member second portion includes a second syringe arm, the first and second syringe arms of the second

syringe engagement member being generally on opposite sides of the alignment axis, the first and second syringe arms of the second syringe engagement member being spaced apart and having concave surfaces sized and shaped to receive the syringe therebetween and to engage and grasp a second convex exterior surface of the syringe which is spaced apart from the first convex exterior surface of the syringe when the syringe is between the first and second syringe arms of the second syringe engagement member and hold the syringe centered on the alignment axis.

29. The device of claim 28 for use with a syringe having a barrel with a needle extending therefrom, wherein the first and second syringe arms of the second syringe engagement member each have a free end positioned spaced apart from the other to provide a gap therebetween of sufficiently large size for lateral passage of the syringe needle therethrough but of sufficiently small size to prevent lateral passage of the syringe barrel therethrough.

30. The device of claim 26 for use with a syringe having a barrel with a needle extending therefrom, wherein the first and second syringe arms of the first syringe engagement member each have a free end positioned spaced apart from the other to provide a first gap therebetween and the first and second syringe arms of the second syringe engagement member each have a free end positioned spaced apart from the other to provide a second gap therebetween, the first and second gaps being in general alignment along the alignment axis, the first and second gaps each being of sufficiently large size for lateral passage of the syringe needle therethrough but of sufficiently small size to prevent lateral passage of the syringe barrel therethrough.

31. The device of claim 30 for use with a syringe barrel having an end portion from which the needle extends, wherein the second syringe engagement member is located between the first syringe engagement member and the vial alignment portion, and wherein the first syringe engagement member further includes a guide surface to engage the barrel end portion, the first and second syringe engagement members being between at least a

portion of the guide surface and the vial alignment portion, the guide surface extending in a direction along the alignment axis away from the vial alignment portion.

32. The device of claim 31 wherein at least a portion of the guide surface extends between the first and second syringe engagement members toward the vial alignment portion.

33. The device of claim 26 for use with a syringe having a barrel with a needle extending from an end portion of the barrel, wherein the first syringe engagement member further includes a guide surface to engage the barrel end portion, the guide surface being at least in part located so that the first and second syringe arms are between the guide surface and the vial alignment portion, the guide surface extending in a direction along the alignment axis away from the vial alignment portion.

34. The device of claim 22 wherein the first syringe engagement member includes a surface which is concave, faces upwardly and extends axially along the alignment axis toward the second syringe engagement member to engage the syringe when the syringe is moved generally downwardly toward the guide surface.

35. The device of claim 22 for use with a syringe having an inclined surface that is inclined relative to the alignment axis and the syringe alignment portion includes a syringe stop surface facing the inclined surface of the syringe and positioned to prevent movement of the syringe beyond a selected position along the alignment axis.

36. The device of claim 22 for use with a syringe having a barrel, a needle projecting from the barrel and a cover covering the needle and removably coupled to the barrel, wherein the body has a needle cover removing portion that includes first and second needle cover engaging surfaces spaced apart to receive and clamp the needle cover therebetween.

37. The device of claim 36 wherein the needle cover engaging surfaces are spaced apart by a distance that is greater than a diameter of the needle cover to allow the needle cover to be positioned between the needle cover engaging surfaces, and at least one of the needle cover engaging surfaces being movable relative to the other to reduce the space between the needle cover engaging surfaces to selectively clamp the needle cover therebetween.

38. The device of claim 36 wherein at least one of the needle cover engaging surfaces includes a sharpened blade.

39. The device of claim 36 for use with a needle cover having a convex surface, wherein at least one of the needle cover engaging surfaces is concave to engage the convex surface of the needle cover.

40. The device of claim 22 for use with a vial having a removable cap with a generally flat upper surface and a cap lip extending around the upper surface and projecting away from the vial, wherein the body includes a cap removing portion having a generally flat receiving surface to receive the upper surface of the cap, the cap removing portion further having an overhanging lip engaging surface opposite the receiving surface and spaced apart sufficiently to receive therebetween and engage the cap lip when the upper surface of the cap is received on the receiving surface.

41. The device of claim 22 for use with a syringe having a barrel with a handle, the handle having at least one flange extending away from the barrel, wherein the body includes a slot for receiving the flange of the handle.

42. The device of claim 41, further comprising a handle stop positioned in the slot to prevent rotation of the handle beyond a selected position.

43. The device of claim 22 wherein the body includes drainage apertures for draining fluid away from the body.

44. A device for aligning a syringe with a vial, the syringe having a needle and a removable cover covering the needle, the device comprising:

a body having a first portion and a second portion spaced apart from the first portion along an alignment axis;

a concave vial clamping member coupled to the body toward the first portion and movable relative to the alignment axis to clamp the vial and restrict motion of the vial transverse to the alignment axis;

a concave syringe clamping member coupled to the body toward the second portion and movable relative the alignment axis to clamp the syringe and restrict motion of the syringe transverse to the alignment axis;

a sharp blade attached to the body; and

a clamping member attached to the body and spaced apart from the sharp blade by a distance sufficient to receive the needle cover therebetween, at least one of the sharp blade and the clamping member being movable relative to the other to clamp the cover of the syringe between the sharp blade and the clamping member.

45. The device of claim 44 for use with a syringe having a barrel with a handle, the handle having at least one flange extending away from the barrel, wherein the body includes a slot for receiving the flange of the handle.

46. The device of claim 45, further comprising a handle stop positioned in the slot to prevent rotation of the handle beyond a selected position.

47. The device of claim 44 for use with a vial having a removable cap with a generally flat upper surface and a lip extending around the upper surface and projecting away from the vial, wherein the body includes a cap removing portion having a generally flat receiving surface to receive the upper surface of the cap, the cap removing portion further

having a lip engaging surface opposite the receiving surface and spaced apart sufficiently to receive therebetween and engage the cap lip when the upper surface of the cap is received on the receiving surface.

48. A storage and shipping container for a vial and a syringe, the container comprising a container body having a first receiving area configured to receive and contain the vial and a second receiving area configured to receive and contain the syringe, the body still further having a vial alignment portion and a syringe alignment portion aligned on an alignment axis extending between the vial alignment portion and the syringe alignment portion, at least one of the vial alignment portion and the syringe alignment portion being different than the first and second receiving areas, the vial alignment portion having a vial engagement surface shaped to engage the vial, the syringe alignment portion having a syringe engagement surface shaped to engage the syringe, at least one of the syringe engagement surface and the vial engagement surface being aligned with the alignment axis to allow axial motion of one of the syringe and the vial relative to the container.

49. The container of claim 48 wherein the body includes an interior surface having the first and second receiving areas and an exterior surface having the vial alignment portion and the syringe alignment portion.

50. The container of claim 49 wherein a portion of the interior surface forms one of the first and second receiving areas and a corresponding portion of the exterior surface forms one of the vial alignment portion and the syringe alignment portion.

51. The container of claim 49 wherein the interior surface includes a floor, perimeter walls projecting away from the floor and a projection projecting away from the floor and spaced apart from the perimeter walls, the first receiving area being at least partially defined by the projection.

52. The container of claim 48 wherein the vial engagement surface includes a first side portion and a second side portion generally opposite the first side portion, the first and second side portions having concave surfaces adjacent the vial, at least one of the first and second side portions being biased toward the other of the first and second side portions to clamp the vial between the side portions.

53. The container of claim 48, further comprising a vial stop positioned to engage the vial and restrict motion of the vial along the alignment axis.

54. The container of claim 53 for use with a vial having a body, a cap, and a neck extending between the cap and the body of the vial, wherein the vial stop projects to a position between the cap and the body of the vial.

55. The container of claim 48 wherein the syringe engagement surface includes a first side portion and a second side portion generally opposite the first side portion, the first and second side portions having facing concave surfaces adjacent the syringe, at least one of the first and second side portions being biased toward the other of the first and second side portions to clamp the syringe between the side portions.

56. The container of claim 55 wherein at least one of the side portions extends at least partially around the syringe to at least restrict motion of the syringe in any direction transverse to the alignment axis.

57. The container of claim 55 wherein at least part of the syringe engagement surface is concave, faces upwardly and extends axially beyond the first and second side portions to receive the syringe when the syringe is moved generally downwardly toward the syringe engagement surface.

58. The container of claim 48 wherein the syringe has an inclined surface that is inclined relative to the alignment axis and the syringe alignment portion includes a

syringe stop surface facing the inclined surface of the syringe to prevent movement of the syringe beyond a selected point along the alignment axis.

59. The container of claim 48 wherein the body has an interior surface and an exterior surface, further comprising a lid removably attached to the container body to prevent motion of the vial and the syringe away from the interior surface and out of the container body.

60. The container of claim 59 wherein the container body includes a generally flat lip extending outwardly from the container body around a periphery of the container body, the lid being removably attached to the lip.

61. A plunger for use with a syringe having a hollow barrel elongated along a barrel axis and a piston movable within the barrel along the barrel axis, the plunger comprising an elongated shaft positionable in the barrel to extend along the barrel axis, the shaft having a first end and a second end opposite the first end, the first end being configured to engage the piston, the shaft including a handle portion toward the second end thereof, the handle portion being elongated transverse to the barrel axis and having a concave surface generally for engagement by a human finger.

62. The plunger of claim 61 wherein the shaft is generally hollow.

63. The plunger of claim 61 wherein the shaft is elongated along a shaft axis and the handle portion includes a plurality of parallel spaced-apart ribs extending generally transverse to the shaft axis.

64. The plunger of claim 61 for use with a piston having first threads, wherein the first end of the shaft includes second threads to threadably engage the first threads of the piston.

65. A handle for use in grasping a barrel of a syringe, the barrel having a first end and a second end opposite the first end, the barrel further having a needle toward the first end and an opening toward the second end, the handle comprising a handle body with a first surface facing generally toward the needle and a second surface facing generally opposite the first surface, the first surface having a first concave engagement region on one side of the barrel for engagement by a first human finger, and a second concave engagement region on an opposite side of the barrel for engagement by a second human finger.

66. The handle of claim 65 for use with a barrel with a lip extending away from the barrel proximate the open second end of the barrel, wherein the first and second surfaces of the handle body are separated by a gap configured to receive the lip therein, at least one of the first and second surfaces of the handle having a tab portion to engage the lip and restrict movement of the lip out of the gap.

67. The handle of claim 65 wherein the handle body is removably attached to the barrel of the syringe.

68. A method for aligning a syringe with a vial, comprising:
securing a first vial by removably engaging the first vial with an alignment body to at least restrict motion of the first vial transverse to an alignment axis extending between the first vial and the syringe;
securing a first syringe by removably engaging the first syringe with the alignment body to at least restrict motion of the first syringe in any direction transverse to the alignment axis such that a needle of the first syringe is aligned with an access port of the vial;
and

reusing the alignment body by removing the first vial and the first syringe therefrom and removably securing a second vial and a second syringe thereto.

69. The method of claim 68 wherein securing the first vial includes restricting motion of the first vial along the alignment axis.

70. The method of claim 68 wherein securing the first syringe includes laterally moving the first syringe toward the alignment body in a direction transverse to the alignment axis, engaging the first syringe with an engagement surface of the alignment body which aligns the first syringe with the alignment axis, and axially moving the first syringe along the engagement surface in general alignment with the alignment axis.

71. The method of claim 68 for use with a first syringe having a barrel, a needle projecting from the barrel and a cover adjacent the needle and removably coupled to the barrel, further comprising clamping the cover between first and second spaced apart cover engaging members of the alignment body and moving the barrel away from the cover while clamped between the first and second cover engaging members to separate the cover from the barrel.

72. The method of claim 71 wherein one of the cover engaging surfaces includes a sharpened blade and clamping the cover includes moving the cover into engagement with the sharpened blade.

73. The method of claim 72 for use with a first vial having a removable cap, further comprising:

engaging the cap with a portion of the alignment body; and
tilting the first vial relative to the alignment body to pry at least one of the cap and the first vial away from the other of the cap and the first vial.

74. The method of claim 68 for use with a first syringe having a barrel and a handle attached to the barrel, wherein securing the first syringe includes engaging the handle with the alignment body.

75. The method of claim 74 for use with a handle having at least one flange extending away from the barrel, wherein securing the first syringe includes rotating the

handle relative to the barrel about an axis generally parallel with the alignment axis and receiving the flange in a slot of the alignment body.

76. The method of claim 75 wherein the aperture includes a handle stop, and securing the first syringe includes rotating the handle until the handle engages the handle stop.

77. The method of claim 68, further comprising:
exposing the alignment body to a cleaning fluid; and
draining the cleaning fluid away from the alignment body through drain apertures in the alignment body.

78. The method of claim 68 wherein securing the first syringe includes grasping the alignment body with one hand and grasping the first syringe with another hand.

79. The method of claim 68 wherein securing the first syringe includes placing the alignment body against a generally flat surface and engaging the first syringe with the alignment body.

80. The method of claim 68 for use with a first vial having a first vial diameter and a first syringe having a first syringe diameter, and with a second vial having a second vial diameter different than the first vial diameter and a second syringe having a second syringe diameter different than the first syringe diameter, further comprising generally aligning the second vial with the second syringe on the alignment axis.

81. A method for preparing a series of syringes for injections, each syringe being usable for a single injection, the method comprising:

securing a vial by removably engaging the vial with an alignment body to at least restrict motion of the vial transverse to an alignment axis extending between the vial and one of the syringes; and

securing the one syringe by removably engaging the one syringe with the alignment body to at least restrict motion of the one syringe in any direction transverse to the alignment axis such that a needle of the one syringe is aligned with an access port of the vial.

82. The method of claim 81 wherein securing the one syringe includes laterally moving the one syringe toward the alignment body in a direction transverse to the alignment axis, engaging the one syringe with an engagement surface of the alignment body which aligns the one syringe with the alignment axis, and axially moving the one syringe along the engagement surface in general alignment with the alignment axis.

83. The method of claim 81 for use with syringes having a barrel, a needle projecting from the barrel and a cover adjacent the needle and removably coupled to the barrel, further comprising clamping the cover between first and second spaced apart cover engaging members of the alignment body and moving the barrel away from the cover while clamped between the first and second cover engaging members to separate the cover from the barrel.

84. The method of claim 81 for use with a vial having a removable cap, further comprising:
engaging the cap with a portion of the alignment body; and
tilting the vial relative to the alignment body to pry at least one of the cap and the vial away from the other of the cap and the vial.

85. A method for aligning a vial with a syringe, comprising:
removing the vial and the syringe from a single container;
engaging the vial with a vial alignment portion of the container;
engaging the syringe with a syringe alignment portion of the container to align the vial with the syringe; and

restricting motion of at least one of the vial and the syringe away from an alignment axis extending between the vial and the syringe by engaging the one of the vial and the syringe with a surface of the container.

86. The method of claim 85, further comprising inverting the container after removing the vial and the syringe and before engaging the vial.

87. The method of claim 85 wherein the container includes a generally flat lip extending around a periphery thereof and inverting the container includes placing the lip face-down on a supporting surface.

88. The method of claim 85 wherein securing the syringe includes moving the syringe toward the alignment body laterally transverse to the alignment axis, engaging the syringe with an engagement surface of the container that is aligned with the alignment axis, and translating the syringe axially along the engagement surface.

89. The method of claim 85 wherein securing the syringe includes placing the container against a generally flat surface and engaging the syringe with the alignment body.

90. A method for removing a protective cover from a syringe, the syringe having a barrel and a needle projecting from the barrel, the cover extending over the needle, the method comprising:

moving the cover against a sharpened edge; and

moving at least one of the sharpened edge and the barrel relative to the other to disengage the cover from the needle.

91. The method of claim 90, further comprising positioning the cover between the sharpened edge and a movable clamping surface, and moving the movable clamping surface toward the sharpened edge with the cover positioned therebetween.

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92. The method of claim 90 wherein the sharpened edge is a portion of an alignment body for aligning the vial and the syringe, further comprising:

securing the vial by engaging the vial with the alignment body to at least restrict motion of the vial transverse to an alignment axis extending between the vial and the syringe; and

securing the syringe by engaging the syringe with the alignment body to at least restrict motion of the syringe transverse to the alignment axis such that a needle of the syringe is aligned with an access port of the vial.

93. A method for engaging a barrel of a syringe, comprising:

positioning the barrel of the syringe between first and second human fingers;

receiving the first finger in a first concave surface of a syringe handle, the syringe handle and the first concave surface extending outwardly away from a first side of the barrel of the syringe; and

receiving the second finger in a second concave surface of the syringe handle extending outwardly away from a second side of the barrel of the syringe generally opposite the first side of the barrel of the syringe.

94. The method of claim 93 wherein the syringe includes a plunger that is movable within the barrel, further comprising at least partially withdrawing the plunger from the barrel while grasping the barrel.

95. A method for moving a plunger in a barrel of a syringe, comprising:

positioning a human finger adjacent the plunger;

receiving the human finger in a concave portion of the plunger; and

moving the human finger relative to the barrel to translate the plunger within the barrel.

96. The method of claim 95 wherein receiving a human finger includes receiving a human thumb in the concave portion of the plunger.

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97. The method of claim 95, further comprising grasping the barrel of the syringe with a human index finger and a human middle finger.

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International Patent Application No. PCT/US99/23594
Applicant: Immunex Corporation et al

CLAIMS

98. A reusable device (24) for aligning a syringe (22) with a vial (20), the device (24) comprising a body (25) having a vial alignment portion (26) and a syringe alignment portion (28) aligned on an alignment axis (30) extending between the vial alignment portion (26) and the syringe alignment portion (28), the vial alignment portion (26) having at least one vial engagement surface shaped to releasably and reusably engage the vial (20) during operation, the syringe alignment portion (28) having at least one syringe engagement surface, shaped to releasably and reusably engage the syringe (22) during operation, the syringe engagement surface including a first portion and a second portion axially offset from the first portion, the first portion being upwardly facing, generally aligned with the alignment axis (30), and having a first opening to freely receive a barrel (56) of the syringe (22) when at least one of the syringe (22) and the body (25) is moved relative to the other in a direction transverse to the alignment axis (30) during operation, the second portion having a second opening smaller than the first opening, with the second portion extending around a portion of the syringe (22) sufficient to at least restrict motion of the syringe (22) in any direction transverse to the alignment axis (30) when at least one of the syringe (22) and the body (25) is moved relative to the other in a direction generally aligned with the alignment axis (30), the first and second portions defining an axial sliding surface to accommodate axial sliding of the syringe (22) during operation.

~~114. A method for aligning a syringe (22) with a vial (20) comprising:~~

NEW CLAIMS 98-124

~~1 98. A reusable device (24) for aligning a syringe (22) with a vial (20), the~~
~~2 device (24) comprising a body (25) having a vial alignment portion (26) and a syringe~~
~~3 alignment portion (28) aligned on an alignment axis (30) extending between the vial~~
~~4 alignment portion (26) and the syringe alignment portion (28), the vial alignment portion (26)~~
~~5 having at least one vial engagement surface shaped to releasably and reusably engage the vial~~
~~6 (20) during operation, the syringe alignment portion (28) having at least one syringe~~
~~7 engagement surface shaped to releasably and reusably engage the syringe (22) during~~
~~8 operation, the syringe engagement surface including a first portion and a second portion~~
~~9 axially offset from the first portion, the first portion being generally aligned with the~~
~~10 alignment axis (30) to receive a barrel (56) of the syringe (22) when at least one of the~~
~~11 syringe (22) and the body (25) is moved relative to the other in a direction transverse to the~~
~~12 alignment axis (30) during operation, the second portion extending around a portion of the~~
~~13 syringe (22) sufficient to at least restrict motion of the syringe (22) in any direction~~
~~14 transverse to the alignment axis (30) when at least one of the syringe (22) and the body (25)~~
~~15 is moved relative to the other in a direction generally aligned with the alignment axis (30)~~
~~16 during operation.~~

1 99. The device (24) of claim 98 wherein the syringe alignment portion (28)
2 includes a first syringe arm (98) and a second syringe arm (98) spaced apart from the first
3 syringe arm (98), the first and second syringe arms (98) having concave surfaces proximate
4 the syringe (22), the concave surfaces being spaced apart by a distance greater than a
5 diameter of the syringe (22) so the syringe (22) fits loosely therebetween, the concave
6 surfaces being spaced closely enough to at least restrict motion of the syringe (22) transverse
7 to the alignment axis (30).

1 100. The device (24) of claim 98 wherein the first portion of the syringe
2 engagement surface is concave, faces upwardly and extends axially beyond the second

3 portion of the syringe engagement surface to receive the syringe (22) when the syringe (22)
4 is moved generally downwardly toward the first portion of the syringe engagement surface.

1 101. The device (24) of claim 98 wherein the syringe (22) includes a barre
2 (56), a needle (58) projecting from the barrel (56) and a cover (60) covering the needle and
3 removably coupled to the barrel (56), further wherein the body (25) has a cover removing
4 portion that includes first and second cover engaging surfaces (108, 110) spaced apart to
5 clamp the cover (60) therebetween.

1 102. The device (24) of claim 101 wherein the cover engaging surfaces (108
2 110) are spaced apart by a distance that is greater than a diameter of the cover (60) to allow
3 the cover (60) to be positioned between the cover engaging surfaces (108, 110), and at least
4 one of the cover engaging surfaces (108, 110) is movable relative to the other.

1 103. The device (24) of claim 101 wherein at least one of the cover engaging
2 surfaces (108, 110) includes a sharpened blade.

1 104. The device (24) of claim 98 wherein the vial (20) includes a removable
2 cap (46) having a generally flat upper surface and a cap lip (48) extending around the upper
3 surface and projecting away from the vial, further wherein the body (25) includes a cap
4 removing portion having a generally flat receiving surface (118) to receive the upper surface
5 of the cap (46), the cap removing portion further having an overhanging lip engaging surface
6 (120) opposite the receiving surface (118) to engage the lip (48) when the cap (46) is
7 received on the receiving surface (118).

1 105. The device (24) of claim 98 wherein the second portion of the syringe
2 engagement surface includes first and second syringe arms (98), and further wherein at least
3 one of the first and second syringe arms (98) is biased toward the other to releasably clamp
4 the syringe (22) between the first and second syringe arms (98) when the syringe (22) is
5 received therebetween and center the syringe (22) generally on the alignment axis (30).

1 106. The device (24) of claim 98 for use with a syringe (22) having a barre
2 (56) with a needle (58) exterior therefrom, wherein the first and second syringe arms (98
3 each have a free end (98a) positioned spaced apart from the other to provide a gap (99
4 therebetween of sufficiently large size for lateral passage of the syringe needle (58
5 therethrough but of sufficiently small size to prevent lateral passage of the syringe barrel (56
6 therethrough.

1 107. The device (24) of claim 98 wherein the second portion of the syringe
2 engagement surface is positioned between the first portion of the syringe engagement surface
3 and the vial.

1 108. The device (24) of claim 98 wherein the vial engagement member
2 includes a first vial arm (52) and a second vial arm (52) generally opposite the first vial arm
3 (52) on opposing sides of the alignment axis (30), the first and second vial arms (52) being
4 spaced apart and having concave surfaces sized and shaped to receive the vial (20)
5 therebetween and to engage and grasp a convex exterior surface of the vial (20) when the vial
6 (20) is between the first and second vial arms (52), at least one of the first and second vial
7 arms (52) being biased toward the other to releasably clamp the vial (20) between the first
8 and second vial arms (52) when received therebetween and center the vial (20) generally on
9 the alignment axis (30).

1 109. The device (24) of claim 98 for use with a vial (20) having at least one
2 inclined surface inclined relative to the alignment axis (30) wherein the vial alignment
3 portion (26) includes a vial stop surface (54) facing the inclined surface of the vial (20) and
4 positioned to prevent motion of the vial (20) beyond a selected position along the alignment
5 axis (30).

1 110. The device (24) of claim 98 for use with a syringe (22) having a barrel
2 (56) with a needle (58) extending therefrom, wherein the first syringe engagement portion
3 has first and second syringe arms (96) generally on opposite sides of the alignment axis (30),
4 the first and second syringe arms (96) being spaced apart and having a concave surface sized

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5 and shaped to loosely receive the syringe (22) therebetween and to at least restrict motion o
6 the syringe (22) transverse to the alignment axis (30) when the syringe (22) is between the
7 first and second syringe arms (96), and wherein the second syringe engagement portion has
8 first and second syringe arms (98) spaced apart and having concave surfaces sized and
9 shaped to grasp a convex exterior of the syringe (22) when the syringe (22) is between the
10 first and second syringe arms (96) of the second engagement portion, at least one of the first
11 and second syringe arms (96) of the second engagement portion being biased toward the
12 other to releasably clamp the syringe (22) therebetween and center the syringe (22) generally
13 on the alignment axis (30), further wherein the first and second syringe engagement arms
14 (96) of the first engagement portion each have a free end (96a) positioned spaced apart from
15 the other to provide a first gap (97) therebetween, the first and second syringe engagement
16 arms (98) of the second engagement portion each having a free end (98a) positioned spaced
17 apart from the other to provide a second gap (99) therebetween, the first and second gaps
18 (97, 99) being in general alignment along the alignment axis (30, the first and second gaps
19 (97, 99) each being of sufficiently large size for lateral passage of the syringe needle (58)
20 therethrough but of sufficiently small size to prevent lateral passage of the syringe barrel (56)
21 therethrough.

1 111. The device (24) of claim 98 for use with a syringe (22) having a barrel
2 (56) with a handle (80), the handle (80) having at least one flange (90) extending away from
3 the barrel (56), wherein the body (25) includes a slot (104) for receiving the flange (90) of
4 the handle (80) and a handle stop (105) positioned in the slot (104) to prevent rotation of the
5 handle (80) beyond a selected position.

1 112. The device (24) of claim 98 wherein the vial alignment portion (26) is
2 fixed relative to the syringe alignment portion (28).

1 113. The device (24) of claim 98 for use with a syringe (22) having at least
2 one inclined surface inclined relative to the alignment axis (30) wherein the syringe
3 alignment portion (28) includes a syringe stop surface (100) facing the inclined surface of the
4 syringe (22) and positioned to prevent motion of the syringe (22) beyond a selected position
5 along the alignment axis (30).

PCT 1178-00155/rw

International Patent Application No. PCT/US99/23594
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CLAIMS

98. ~~A reusable device (24) for aligning a syringe (22) with a vial (20), the device (24) comprising a body (25) having a vial alignment portion (26) and a syringe alignment portion (28) aligned on an alignment axis (30) extending between the vial alignment portion (26) and the syringe alignment portion (28), the vial alignment portion (26) having at least one vial engagement surface shaped to releasably and reusably engage the vial (20) during operation, the syringe alignment portion (28) having at least one syringe engagement surface, shaped to releasably and reusably engage the syringe (22) during operation, the syringe engagement surface including a first portion and a second portion axially offset from the first portion, the first portion being upwardly facing, generally aligned with the alignment axis (30), and having a first opening to freely receive a barrel (56) of the syringe (22) when at least one of the syringe (22) and the body (25) is moved relative to the other in a direction transverse to the alignment axis (30) during operation, the second portion having a second opening smaller than the first opening, with the second portion extending around a portion of the syringe (22) sufficient to at least restrict motion of the syringe (22) in any direction transverse to the alignment axis (30) when at least one of the syringe (22) and the body (25) is moved relative to the other in a direction generally aligned with the alignment axis (30), the first and second portions defining an axial sliding surface to accommodate axial sliding of the syringe (22) during operation.~~

114. A method for aligning a syringe (22) with a vial (20) comprising:

securing a first vial (20) by removably engaging the first vial (20) with an alignment body (25) to at least restrict motion of the first vial (20) transverse to an alignment axis (30) extending axially from an access port (42) of the first vial (20) when the first vial is secured;

securing a first syringe (22) by laterally moving the first syringe (22) toward the alignment body (25) in a direction transverse to the alignment axis (30), engaging a barrel (56) of the first syringe (22) with a first engagement surface of the alignment body (25) which aligns the first syringe (22) with the alignment axis (30), and axially moving the first syringe (22) along the first engagement surface in general alignment with the alignment axis (30) to engage the syringe (22) with a second engagement surface and at least restrict motion of the first syringe (22) in any direction transverse to the alignment axis (30) such that a needle (58) of the first syringe (22) is aligned with and the access port (42) of the vial (20); and

reusing the alignment body (25) by removing the first vial (20) and the first syringe (22) therefrom and removably securing a second vial (20) and a second syringe (22) thereto.

1 ~~114. A method for aligning a syringe (22) with a vial (20), comprising:~~
2 securing a first vial (20) by removably engaging the first vial (20) with an
3 alignment body (25) to at least restrict motion of the first vial (20) transverse to an alignment
4 axis (30) extending between the first vial (20) and the syringe (22);
5 securing a first syringe (22) by laterally moving the first syringe (22) toward
6 the alignment body (25) in a direction transverse to the alignment axis (30), engaging a barrel
7 (56) of the first syringe (22) with a first engagement surface of the alignment body (25)
8 which aligns the first syringe (22) with the alignment axis (30), and axially moving the first
9 syringe (22) along the first engagement surface in general alignment with the alignment axis
10 (30) to engage the syringe (22) with a second engagement surface and at least restrict motion
11 of the first syringe (22) in any direction transverse to the alignment axis (30) such that a
12 needle (58) of the first syringe (22) is aligned with an access port (42) of the vial (20); and
13 reusing the alignment body (25) by removing the first vial (20) and the first
14 syringe (22) therefrom and removably securing a second vial (20) and a second syringe (22)
15 thereto.

1 115. The method of claim 114 wherein securing the first vial (20) includes
2 restricting motion of the first vial (20) along the alignment axis (30).

1 116. The method of claim 114 for use with a first syringe (22) having a barrel
2 (56), a needle (58) projecting from the barrel (56) and a cover (60) adjacent the needle (58)
3 and removably coupled to the barrel (56), further comprising clamping the cover (60)
4 between first and second spaced apart cover engaging members (108, 110) of the alignment
5 body (25) and moving the barrel (56) away from the cover (60) while clamped between the
6 first and second cover engaging members (108, 110) to separate the cover (60) from the
7 barrel (56).

1 117. The method of claim 115 wherein one of the cover engaging surfaces
2 (108, 110) includes a sharpened blade and clamping the cover (60) includes moving the
3 cover (60) into engagement with the sharpened blade.

1 118. The method of claim 114 for use with a first vial (20) having a
2 removable cap (46), further comprising:
3 engaging the cap (46) with a portion of the alignment body (25); and
4 tilting the first vial (20) relative to the alignment body (25) to pry at least one
5 of the cap (46) and the first vial (20) away from the other of the cap (46) and the first vial
6 (20).

1 119. The method of claim 114 for use with a first syringe (22) having a barrel
2 (56) and a handle (80) attached to the barrel (56), wherein securing the first syringe (22)
3 includes engaging the handle (80) with the alignment body (25).

1 120. The method of claim 119 for use with a handle (80) having at least one
2 flange (90) extending away from the barrel (56), wherein securing the first syringe (22)
3 includes rotating the handle (80) relative to the barrel (56) about an axis generally parallel
4 with the alignment axis (30) and receiving the flange (90) in a slot (104) of the alignment
5 body (25).

1 121. The method of claim 120 wherein the slot (104) includes a handle stop
2 (105), and securing the first syringe (22) includes rotating the handle (80) until the handle
3 (80) engages the handle stop (105).

1 122. The method of claim 114 wherein securing the first syringe (22)
2 includes grasping the alignment body (25) with one hand and grasping the first syringe (22)
3 with another hand.

1 123. The method of claim 114 wherein securing the first syringe (22)
2 includes placing the alignment body (25) against a generally flat surface (124) and engaging
3 the first syringe (22) with the alignment body (25).

1 124. The method of claim 114 for use with a first vial (20) having a first vial
2 diameter and a first syringe (22) having a first syringe diameter, and with a second vial (22)

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- 3 having a second vial diameter different than the first vial diameter and a second syringe (20)
- 4 having a second syringe diameter different than the first syringe diameter, further comprising
- 5 generally aligning the second vial (20) with the second syringe (22) on the alignment axis
- 6 (30).

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AMENDED SHEET